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Postapproval outcomes of juxtarenal aortic aneurysms treated with the Zenith fenestrated endovascular graft

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Objective: **The objective of this study was to evaluate postapproval outcomes of patients with juxtarenal aortic aneurysms treated with the Zenith fenestrated endovascular graft (Cook Inc, Bloomington, Ind).**
Methods: **We reviewed clinical data of consecutive patients treated with the Zenith fenestrated endovascular graft in the United States at seven institutions with early commercial access from July 2012 to December 2012. Clinical outcomes and compliance to anatomic guidelines were compared with results of the U.S. fenestrated trial (USFT).**
Results: **Fifty-seven patients were treated. There were significantly more ($P < .05$) patients with coronary artery disease, myocardial infarction, and preoperative renal insufficiency than in the USFT. Thirty-six patients (63.2%) did not meet the USFT anatomic criteria of a >4-mm infrarenal neck, and there were significantly more mesenteric stents (13 vs 0; $P < .05$) used in this group than in the USFT, reflecting the higher anatomic complexity of these patients. The total operative time was 250.2 ± 14.8 minutes, the fluoroscopy time was 68.9 ± 4.47 minutes, and the average volume of contrast material was 108.6 ± 5.6 mL. Technical success was 100% in regard to aneurysm exclusion, although the left renal fenestration was not able to be aligned in two patients, and one patient had a kinked renal stent that was successfully restented. During this time period, there were a total of 10 endoleaks, of which two were type III and eight were type II.**
Conclusions: **Despite higher rates of comorbidities and more challenging anatomy, early 30-day outcomes of juxtarenal aortic aneurysms treated postapproval with the Zenith fenestrated endovascular graft compare well with USFT data. Future studies are needed to assess durability of this treatment modality as the technology diffuses and data mature. (J Vasc Surg 2014;60:295-300.)**

The surgical management of abdominal aortic aneurysms (AAAs) has gone through tremendous change with the introduction and evolution of endovascular technology. There has been a dramatic increase in the number of infrarenal aortic aneurysms treated with endovascular therapy. However, U.S. Food and Drug Administration (FDA)–approved solutions to juxtarenal aortic aneurysms (JRAAs) did not exist and therefore the surgical management of JRAAs has predominantly remained open surgery in the United States.[1,2] There has been significant innovation in the endovascular management of these patients with techniques including "snorkeling," chimney grafts, and custom endografts. However, these rescue and custom techniques used in elective cases do not uniformly produce excellent results.[3-8] From this clinical need, endovascular therapy is being developed to treat AAAs with innovate technologies, allowing the treatment of aneurysms with maintenance of visceral branch vessel flow. The Zenith fenestrated device (Cook Inc, Bloomington, Ind) is a device that can treat AAAs with a short infrarenal neck and is custom-made with scallops and fenestrations to accommodate the branch vessels as needed. The pivotal U.S. fenestrated trial (USFT) revealed excellent outcomes and resulted in FDA approval of the device.[9] The purpose of our study was to review the outcomes of the device in routine clinical use without the limitations of trial inclusion criteria.

METHODS

Patient selection. A retrospective review was performed of all patients with the diagnosis of AAA undergoing endovascular repair with the Zenith fenestrated endovascular graft (zFEN) from July 1, 2012, through

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December 31, 2012. This study included seven institutions in the United States: Washington University, St. Louis, Mo; Indiana University, Indianapolis, Ind; New York University, New York, NY; University of North Carolina, Chapel Hill, NC; Stanford University, Palo Alto, Calif; University of Pennsylvania, Philadelphia, Pa; and Mayo Clinic, Rochester, Minn. Institutional review board approval was gained as required by each institution. The diagnosis of AAA was made on the basis of radiologic review of preoperative imaging, which was most often computed tomography (CT) angiography or, alternatively, magnetic resonance angiography.

The patient's imaging was used to create a customized layout for the fenestrated device, which was reviewed by Cook Inc before production of the device. In the planning stages, there are several important considerations outlined in Cook's instructions for use: the access vessels must be able to accommodate a 14F to 22F sheath; aortic angulation from the suprarenal to the infrarenal neck or the infraneck to the main aortic axis should not exceed 45 degrees; the infrarenal aortic neck should be at least 4 mm; and there should not be more than a 10% increase in the diameter of the aortic neck through the intended seal zone. In addition, there are limitations on the configurations: a maximum of three fenestrations (only two can be of the same size) or a maximum of two fenestrations with a single scallop.

Procedure. Each operator reviewed preoperative high-resolution imaging and ordered a graft that was then manufactured by the company. Devices were implanted with techniques similar to those of the USFT. Percutaneous or open femoral access as well as the choice of renal or visceral stent implantation was at the discretion of the operator. All operators used Atrium's iCAST stent (Atrium Medical, Hudson NH) for branch vessel stenting. After implantation of the proximal fenestrated component, the bifurcated main body and limbs were placed as in a standard endovascular aneurysm repair. All components were molded, and completion angiography was performed if it was deemed necessary. Postoperative antiplatelet therapy regimens varied and included the following: aspirin only; aspirin and clopidogrel indefinitely; aspirin and clopidogrel (only 1 month); and aspirin and clopidogrel (3 months).

Surveillance and imaging protocol. Whereas the specific surveillance and imaging protocol strategies were left to the discretion of the treating physician, all patients were admitted to the hospital after the procedure and had noninvasive imaging at the time of follow-up. The timing and use of imaging at follow-up were left to the discretion of each treating physician. Standard 1-month follow-up should include an office visit and a three-phase CT scan. If there is no evidence of endoleak, yearly follow-up with repeated CT scans is sufficient. However, if there is an endoleak, the scan should be repeated in 3 to 6 months to assess the need for reintervention. Currently, there is no consensus on the routine use of duplex ultrasonography to assess branch vessel stent grafts in this setting. In addition, magnetic resonance cannot be used to image patients as the branch vessel stent grafts are constructed with steel.

Analysis. Medical records were reviewed, and patient-specific information including demographics, vascular vessel measurements, preoperative variables, postoperative variables, operative details, and clinical data were extracted. We excluded patients who did not undergo repair of AAA with zFEN. Statistical analysis was performed by the unpaired, two-tailed *t*-test and Fisher's exact test.

RESULTS

During the 6-month study period, 57 consecutive patients underwent endovascular repair of JRAAs with zFEN and were included for review in comparison to patients in the USFT. Table I summarizes preoperative and intraoperative variables. The definition of each of the variables was at the discretion of the treating physician. The mean age of patients was 73.3 years in this study compared with 75.3 years in the USFT ($P = .76$). There were 46 men (86.8%) in this study compared with 33 (78.6%) in the USFT ($P = .81$) There were significantly more ($P < .05$) patients with coronary artery disease, myocardial infarction, congestive heart failure, and preoperative renal insufficiency than in the USFT (Table I).

The average maximal aneurysm diameter was 60.6 mm (standard error of the mean [SEM], ± 1.4). The average aortic diameter at the celiac artery was 26.1 mm (SEM, ± 0.42); at the superior mesenteric artery (SMA), 24.4 mm (SEM, ± 0.48); and at the lowest renal artery, 26.0 mm (SEM, ± 0.98). The average neck diameter was 26.2 mm (SEM, ± 0.57). The aortic neck length was defined as the distance from the lowest renal artery to the beginning of the aneurysm. The average neck length was 3.47 mm (SEM, ± 0.47). Thirty-six patients (63.2%) did not meet the USFT anatomic criteria of a >4-mm infrarenal neck. Therefore, the graft configurations were more complex. The most common graft configuration was used in 36 patients (63%). This was a scallop for the SMA and bilateral renal artery fenestrations. Eight patients (14%) had only bilateral renal artery fenestrations. Five patients (8.8%) had three fenestrations for the SMA and bilateral renal arteries. Two patients (3.5%) had left renal artery fenestrations only. The following configurations were each used once: celiac scallop with SMA and bilateral renal artery fenestrations, right accessory renal artery fenestration, right renal artery fenestration only, right renal artery scallop with a left renal artery fenestration, SMA and right renal artery fenestration, and SMA scallop with a left renal artery fenestration. Thirteen patients underwent mesenteric artery stenting compared with none in the USFT. Of these, two were celiac stents and 11 were SMA stents (Table II).

All cases were performed on an elective basis; however, three patients were treated because of the rate of enlargement (>5 mm in 6 months). The total operative time was 250.2 minutes (±14.8), the fluoroscopy time was 68.9 minutes (±4.47), and the average volume of contrast material was 108.6 mL (±5.6). Aneurysm exclusion was achieved in 100% of the cases as verified by completion angiography. The average estimated blood loss was 543.5 mL ± 116.1 (SEM). The majority of patients did

Table I. Patient demographics

Preoperative variables	*Study patients (n = 57)*	*zFEN trial patients (n = 42)*[a]	P *value*
Age, years	73.3	75.3	.76
Male	46 (86.8)	33 (78.6)	.81
Coronary artery disease	45 (79)	22 (52.4)	<.05
Myocardial infarction	34 (59.6)	10 (23.8)	<.05
Chronic obstructive pulmonary disease	21 (36.8)	14 (33.3)	.83
Renal insufficiency	15 (26.3)	4 (9.5)	<.05
Diagnosis of congestive heart failure	25 (44)	4 (9.5)	<.05
Diagnosis of cardiac arrhythmia	13 (22.8)	17 (40.5)	.077
Peripheral vascular disease	23 (40.4)	10 (23.8)	.13
Hypertension	56 (98)	39 (92.9)	.31
Preoperative renal failure requiring hemodialysis	0 (0)	0 (0)	0
Diabetes	10 (17.5)	11 (26.2)	.33
Diagnosis of cerebrovascular disease	8 (14.0)	7 (16.7)	.78
Smoking history			
Never smoked	4 (7.0)	6 (14.3)	.32
Quit smoking	36 (63.2)	24 (57.1)	.86
Actively smoker	17 (29.8)	12 (28.6)	1.0
Body mass index[b]	29.4 ± 4.39 (21.5-40)	28.7 ± 4.8 (19.5-40.8)	.92

zFEN, Zenith fenestrated endovascular graft.
Data are presented as number (%) unless otherwise indicated.
[a]https://www.cookmedical.com/zenith/fenestrated/resources/IFUFU%20%20Zenith%20Fenestrated%20AAA%20Endovascular%20Graft%20-%20US.pdf.
[b]Body mass index calculated by height (m^2)/weight (kg), mean values ± standard deviation.

Table II. Presenting anatomic dimensions and intraoperative variables

	Study patients (n = 57)	*zFEN trial patients (n = 42)*[a]	P *value*
Diameter at celiac artery, mm ± SEM	26.1 ± 0.42	28.2 ± 3.2	.45
Diameter at SMA, mm ± SEM	24.4 ± 0.48	28 ± 3.5	.24
Diameter at lowest patent renal artery, mm ± SEM	26.0 ± 0.98	25.7 ± 3.2	.92
Maximum aortic diameter, mm ± SEM	60.6 ± 1.4	61.1 ± 10.9	.96
Average neck length,[b] mm ± SEM	3.47 ± 0.47	4.0[c]	
Vessel stenting			
Celiac	2	0	
SMA	11	0	
Right renal	55	38	
Left renal	52	40	

AAA, Abdominal aortic aneurysm; *SEM,* standard error of the mean; *SMA,* superior mesenteric artery; *zFEN,* Zenith fenestrated endovascular graft.
[a]https://www.cookmedical.com/zenith/fenestrated/resources/IFUFU%20%20Zenith%20Fenestrated%20AAA%20Endovascular%20Graft%20-%20US.pdf.
[b]Distance from the lowest renal artery to the beginning of the AAA.
[c]Study participation required a minimum of a 4-mm neck.

not require brachial access (88%) and had open femoral exposures. Ten patients (18%) had percutaneous access for the main body, and nine patients (16%) had percutaneous access for the contralateral limb. In one case, the contralateral limb was deployed outside of the distal main body. This was successfully corrected with placement of a right aorto-unibody graft, a right to left femoral-femoral bypass, and an iliac occluder plug in the malpositioned left iliac limb. Five concomitant procedures were performed, including right common femoral artery interposition graft (one), iliac conduits (two), treatment of right iliac artery aneurysm with embolization and endovascular exclusion (one), and celiac artery stent to treat an angiographic critical stenosis (one).

The mean length of stay was 4.33 days (±0.43, SEM). There were three patients (5.3%) in whom the surgeon was unable to align the left renal fenestration, resulting in coverage of the orifice of the left renal artery by the graft. In those three cases, the left kidney remained devascularized. The average discharge creatinine concentration for those patients was 1.19 mg/dL (±0.09, SEM) with a range of 1.1 to 1.3 mg/dL, and none of those patients needed short- or long-term hemodialysis. In addition, none of those patients had immediate or late endoleaks. There was one mortality during the study period. The patient was a 77-year-old man who had had a prior aneurysm repair with an AneuRx device (Medtronic, Santa Rosa, Calif). The device had migrated inferiorly and was severely angulated with multiple kinks. The patient, during routine follow-up, was noted to have developed a 9-cm juxtarenal aneurysm. The zFEN procedure was technically challenging and complex and involved bilateral renal artery stenting, SMA stenting, and bilateral stents at the aortic bifurcation. The procedure was 608 minutes, with

137 minutes of fluoroscopy and 6500 mL of estimated blood loss. The procedure was a technical success, but the patient developed multiorgan failure and died on postoperative day 2. One patient had postoperative pneumonia. Four patients had a postoperative dysrhythmia, and four patients had postoperative acute renal failure that did not require hemodialysis. Of the patients with acute renal failure, one patient required hemodialysis, and that was the patient who ultimately died. The average change in creatinine concentration for the other three patients was 0.50 mg/dL (±0.27, SEM), with a range of 0.6 to 0.9 mg/dL. There were no reported visceral stent thromboses, limb occlusions, myocardial infarctions, strokes, or wound complications.

The average length of follow-up was 52.7 days (±6.17, SEM; range, 2-193 days) in 50 patients. At follow-up, there were no reported wound complications, renal or visceral stent thromboses, or limb occlusions. One patient was noted to have had a myocardial infarction, and one patient was noted to have had a stroke. In addition, one patient had a kinked renal artery stent requiring reintervention with successful additional stent placement on the second postoperative day. During the study time, 10 endoleaks were reported. Eight patients (14%) had type II endoleaks, and two patients (3.5%) had type III endoleaks. Both type III endoleaks were between the proximal main body and the renal fenestration. One was treated with restenting through the existing renal artery stent; the other was treated with angioplasty of the renal artery stent, the fenestrated component, and additional remolding. There were a total of 120 visceral vessels to be treated, with 117 successfully treated, resulting in an immediate target vessel patency of 97.5% (Table III).

Table III. Thirty-day outcomes

	Study patients	*zFEN trial patients*[a]	P *value*
Technical success	57 (100)	42 (100)	1.00
All-cause mortality	1 (1.75)	0 (0)	1.00
AAA-related mortality	0 (0)	0 (0)	1.0
Rupture	0 (0)	0 (0)	1.0
Conversion	0 (0)	0 (0)	1.0
Renal insufficiency	4 (7.02)	0 (0)	.13
Postoperative dialysis	1 (1.75)	0 (0)	1.00
Migration	0 (0)	0 (0)	1.0
Fenestration stent fracture	0 (0)	0 (0)	1.0
Myocardial infarction	0 (0)	0 (0)	1.0
Paralysis	1 (1.75)	0 (0)	1.0
Stroke	1 (1.75)	0 (0)	1.0
Wound complications	0 (0)	1 (2.44)	.42
Renal	1 (1.75)	0 (0)	1.0
Limb occlusion	0 (0)	0 (0)	1.0
Endoleak	10 (17.5)	9 (21.4)	.62
Total	10	9	
Type I proximal	0	0	
Type I distal	0	0	
Type II	8	9	
Type III	2	0	
Type IV	0	0	
Unknown	0	0	
Reintervention	2	1	1.0

AAA, Abdominal aortic aneurysm; *zFEN,* Zenith fenestrated endovascular graft.

Data are presented as number (%).

[a]https://www.cookmedical.com/zenith/fenestrated/resources/IFUFU%20%20Zenith%20Fenestrated%20AAA%20Endovascular%20Graft%20-%20US.pdf.

DISCUSSION

A significant portion of patients with infrarenal AAAs have aortic neck anatomy that makes them unsuitable for traditional endovascular aneurysm repair.[10] The operative management of JRAAs is challenging through the traditional open or endovascular approach. There are currently no randomized studies to compare outcomes from open and endovascular treatment. A study comparing grouped endovascular and open surgical series revealed an increased mortality of 2% for open repair.[11]

Early techniques to treat these aneurysms relied on inventive approaches heralded by skilled physicians. From the first reports published in 1999 to early small series on the treatment of AAAs with fenestrated grafts, the feasibility was proved.[12-15] In 2004, multiple studies were published that revealed a promising initial experience with zFEN. These initial studies had 18 to 32 patients and a 4.5% to 6.5% early endoleak rate with a total of three deaths.[16-18] Over time, experience with zFEN increased, and multiple published studies showed a high technical success rate, but they did reveal the potential for a significant rate of endoleaks, major complications, and a potential need for conversion to open repair.[19-24] The USFT provided excellent data on the ability of zFEN to treat JRAAs, and it was approved for use in April 2012. zFEN is the first FDA-approved graft, and we intended to review the early postapproval outcomes.

The primary goal of aneurysm repair is aneurysm exclusion, which was accomplished in 100% of the 57 patients in this series. However, these cases were technically challenging as many did not have a 4-mm or greater infrarenal neck as required in the USFT. This resulted in more complex graft configurations, and, in this study, scallops that were at risk for minimal misalignment and visceral fenestrations were stented.

In this series, three left renal fenestrations were unable to be aligned, resulting in loss of perfusion to a kidney in each case, but none of those patients required hemodialysis. One patient who had acute renal failure was found to have a thrombosed renal stent secondary to kinking of that stent. The patient underwent reintervention with successful restenting of that renal stent and has had no long-term sequelae to date. There were a number of early endoleaks, eight were type II and only two were type III. One type III endoleak was noticed on completion angiography and resolved with remolding of a renal stent to the fenestrated graft junction. The other type III endoleak was successfully treated with restenting of a renal artery stent. The remaining patients with type II endoleaks are being observed and will be treated if it is clinically appropriate.

Regarding the one early postoperative death, we have learned that there can come a point in cases of this level of complexity at which the desired outcome cannot be achieved and persistence to achieve technical success can result in demise of the patient. Specifically in this case, the patient did not tolerate the length of the procedure and blood loss and developed multisystem organ failure.

The treatment of JRAAs with zFEN requires significant preoperative planning with high-resolution preoperative imaging. As many other authors have discussed, there are unique considerations to the implantation of a fenestrated device.[16,17,19,20] Vascular access must be suitable to accommodate a fenestrated device, and an iliac conduit may be needed for this reason. In addition, one must carefully plan and measure the location and size of visceral and renal vessels to design the graft. A minimally misaligned scallop or fenestration could result in the need for unanticipated stent placement or loss of a vessel. Furthermore, appropriate alignment may require significant rotation of the graft in the aortic neck. This raises at least two issues, including the risk of embolism from thrombus in the neck and the possibility that the neck may not be large enough to allow adequate rotation. Once the fenestrated components are in place, molding must be done perfectly to avoid type III endoleaks and to maintain visceral and renal vessel patency. After placement of the fenestrated portion, the remainder of the procedure has to be performed without disruption of the fenestrated component and its branches.

One final point is simple logistics. These grafts can take 6 weeks to be constructed. Thus, patients who are symptomatic, emergent, or urgent or have AAAs that have signs concerning for impending rupture should not be candidates. An increasing number of off-the-shelf options are being developed to accommodate those patients. Experience with these is limited but growing, and it will be interesting to see how these perform not only in the emergent setting but electively in comparison to zFEN.[25-27]

As this technology diffuses and its application is left to the discretion of the treating physicians, significant issues may arise. There will undoubtedly be a learning curve for device implantation that involves not only procedural techniques but preoperative and postoperative management. As an example, in this study, one patient's renal vessel patency was rescued as acute renal failure was diagnosed early; appropriate imaging was available and performed, and the correct reintervention was completed in a timely fashion. Physicians will need to learn the preoperative anatomic factors that may make cases challenging and to make appropriate plans to ensure excellent outcomes. Long-term success will likely be found to be dependent on selection of the proper neck and on assessment of the ability to stent diseased branch vessels. Ideally, hospitals performing these procedures are equipped with the necessary diagnostic and interventional capabilities to rescue patients from complications. It is unclear at this time if outcomes for zFEN implantation will correlate to surgeon volume or hospital volume. In addition, we do not know how the device will perform in the short, mid, and long term in patients with aortic anatomy more complex than reported in this and the other cited studies.

The long-term results of open repair of AAAs are well known. The natural history of the aorta proximal to the repair and the modalities of treatment failure have been studied. Large centers have repeatedly reported excellent outcomes. For zFEN to become an accepted treatment modality, it too must have excellent long-term treatment outcomes. Although there are short-term and mid-term results, long-term results are currently lacking. Future studies will need to report on graft performance over time in regard to continued aneurysm exclusion, but there are also unique modes of failure for which we will need to acquire data. Specifically, even minimal device migration could result in kinking of visceral or renal stents and loss of perfusion to the viscera or kidneys. The long-term complications of the variety of stents placed in the celiac artery, SMA, and renal arteries need to be examined in this specific context as well as in regard to the development of endoleaks. It will also be interesting to gain an understanding of how the proximal neck will behave over time and if late type Ia endoleaks will develop.

There are several limitations to this study. As noted before, the majority of investigators are highly experienced and skilled endovascular surgeons. Thus, their excellent outcomes may be reflective of this skill and may not translate broadly. In addition, the data have limited follow-up, and ultimately we will need to know the durability of this treatment over years. Furthermore, this was not a randomized trial, and therefore one cannot exclude selection bias in the choice of patients for endovascular repair. The decision between open and endovascular repair of JRAAs was at the discretion of the treating physician and involved factors such as the patient's preference, the patient's willingness for long-term follow-up with CT, anatomy suitable for zFEN, a clinical situation appropriate for a wait of 4 to 6 weeks, and the patient's ability to tolerate an open operation. Also, all of these cases were performed in a controlled, elective setting, and therefore one cannot draw any conclusions about the performance of zFEN in emergent settings assuming a stock of premade grafts were to be made available.

CONCLUSIONS

The results of this study highlight excellent early outcomes of JRAAs treated with zFEN by experienced physicians. This technology will provide physicians with a safe, effective endovascular therapeutic option for complex patients with complex aortic disease. Going forward, we need to analyze long-term outcomes of these patients and assess how the device performs across varied levels of physician experience and patient complexity.

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AUTHOR CONTRIBUTIONS

Conception and design: CV, GO, LS
Analysis and interpretation: CV, MF, JL, GO, LS
Data collection: CV, EW, AF, NC, MF, GO, LS
Writing the article: CV, LS
Critical revision of the article: CV, EW, MF, GO, LS
Final approval of the article: CV, LS
Statistical analysis: CV, LS
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Overall responsibility: CV, LS

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